

Remarks

1. Claims 1-16 were originally filed in the application. Claims 1-16 are rejected in the Office Action. Claim 17 is added by the amendment. Claims 1-17 are pending in this application.
2. Claim 1 has been amended to clarify that the temperature is given in Celsius at which the viscosity of viscoelastic preparation is to be measured.
3. In the Office Action claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, claim 11 depends on itself. Claim 11 has been amended to properly depend from claim 1.
4. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nordquist, et al. Nordquist, et al. discloses chitosan-derived biomaterials wherein the chitosan is glycated with sugars, including galactose. As noted in the Office Action, the instant invention differs from the teaching of Nordquist, et al. in that the viscosity of the solutions are not disclosed. Overlooked in the Office Action is that Nordquist, et al. also does not disclose the molecular weight of its resulting solution and at least one protocol of Nordquist is limited to the production of a galactose derivative of chitosan which is 1.0% by weight of chitosan (Col. 10, lines 13-15).

Claim 1, on the other hand, is drawn to a viscoelastic preparation comprising **greater than 1 percent by weight of a glycated chitosan polymer** dispersed in an aqueous solution, the glycated chitosan polymer having a molecular weight of greater than 100,000 Daltons, said aqueous solution having a viscosity greater than 10,000 centistokes measured at 25° C and a pH in the range of 5.5 to 7.5 (emphasis added).

The Office Action states that “in view of the amounts of solvent and ingredients used in the examples, overlapping compositions would appear to be formed.” The Office Action relies on the similarities between examples given in the Specification and the disclosure of Nordquist, et al. rather than addressing the preparation actually claimed.

In the Office Action, it is stated that:

It would have been prima facie obvious at the time the invention was made to one of ordinary skill in the art to start with the teaching of Nordquist et al., to make applicants compositions and to expect them to be useful in the treatment of cancer, in skin substitutes, pharmaceutical formulations, etc. The exact ratio of reactants and strength of solution could be determined empirically pending on the use.

The standard applied in this context is the “obvious to try” test which is not the standard under 35 U.S.C. § 103. The statutory mandate is for the invention as a whole.¹

[a]pplication of the “obvious to try” test would often deny patent protection to inventions growing out of well-planned research which is, of course, guided into those areas in which success is deemed most likely. These are, perhaps, the obvious areas to try. But resulting inventions are not necessarily obvious. Serendipity is not a prerequisite to patentability.²

While Applicant agrees that Nordquist, et al. would be a logical starting point to make compositions useful for the treatment of cancer, such compositions are not inherently useful for skin substitutes, pharmaceutical formulations, and the like, at least to the same degree as the compositions of the present invention. In fact, it is the viscosity and the extent of glycation which make preparations constructed according to claim 1 particularly useful in these applications. Nordquist,

¹ *In re Lindell*, 385 F.2d 453, 155 USPQ 521, 523 (C.C.P.A. 1967).

² *Id.*

et al. provides an invitation to try but certainly does not enable one to practice the present invention absent guided research.

While the Office Action does not state that the present claims are anticipated by Nordquist, et al., it does suggest that overlapping compounds are formed. In light of the fact that viscosity and glycation as applied in the present invention are not discussed by Nordquist, et al., overlap depends on some degree of inherency. The Federal Circuit has cautioned that inherency:

[m]ay not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.³

It is also insufficient to do no more than broadly allege that claim limitations are disclosed in the prior art, either expressly or inherently.⁴ In the Office Action it is stated that overlapping compounds “would appear to be formed.” There simply is not an adequate foundation in the Office Action to reject claim 1 as being inherent in the Nordquist, et al. disclosure.

Applicant submits that claim 1, 15, and 16 are therefore in condition for allowance. Claims 2-14 depend from claim 1 and, at least for the reasons stated with regard to claim 1, are likewise in condition for allowance. Reexamination and allowance of claims 1-16 are respectfully requested.

Considering the foregoing, it is sincerely believed that this case is in a condition for allowance, which is respectfully requested.

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³ *Continental Van Co. USA v. Monsanto Co.* 948 F.2d 1264, 1269 20 USPQ.2d 1746, 1749 (Fed. Cir. 2001) (quoting *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (C.C.P.A. 1981)).

⁴ *Electro Scientific Industries, Inc. v. General Scanning, Inc.*, 247 F.3d 1341, 58 USPQ.2d 1498 (Fed. Cir. 2001).

This paper is intended to constitute a complete response to the outstanding Office Action. Please contact the undersigned if it appears that a portion of this response is missing or if there remain any additional matters to resolve. If the Examiner feels that processing of the application can be expedited in any respect by a personal conference, please consider this an invitation to contact the undersigned by phone.

Respectfully submitted,

6/11/03

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